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Dockets Management Branch (FDA-305)
Food and Drug Administration
5630 Fishers Lane, Room1061
Rockville, Maryland 20852

RE: ABRA Comments on FDA Guidance for Industry
Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Contacts

Dear Sirs/Madams:

On behalf of its member companies, ABRA is submitting these comments to the Food and Drug Administration (FDA) regarding its draft Guidance for Industry regarding measures to reduce the risk of zoonoses transmission through blood and blood products (hereinafter, the Draft Guidance). ABRA is the trade association and standards setting organization for the Source Plasma collection industry. Source Plasma is the starting material for the manufacture of many life-saving and life sustaining medicines. Each year over one million people worldwide rely on Source Plasma-derived medicines.

Our purpose in commenting on the Draft Guidance is to express concern about the impact it could have blood and plasma collections and the availability of plasma-derived medicines. We believe that the perceived theoretical benefits of the Draft Guidance are greatly outweighed by these likely negative consequences. Further, we believe adequate measures are in place to assure that xenotransplantation recipients do not become blood or plasma donors and that any product quarantine or recall determinations should be made on a case-by-case basis. For these reasons, we believe the Draft Guidance, as currently written, is unwarranted.

Adequate Procedures Are In Place to Prevent Donation by Xenotransplantation Recipients

ABRA and its members agree that xenotransplantation recipients should not be permitted donate blood or plasma. However, the donor screening questions proposed in the Draft Guidance are too long and convoluted to be meaningful. It is likely that these questions would serve only to scare and confuse prospective donors without providing any incremental gain in safety. Given the current need

for attracting new donors and increasing donation frequency, we believe the proposed questions should be eliminated.

Moreover current donor screening procedures likely exclude such donors. Prior to the first donation, donors are given a brief physical examination and a health history is obtained. Donors also are routinely asked if they are under a doctor's care, had any recent surgery or medical procedures, or received any organ or tissue transplants. This health history screening is adequate to exclude xenotransplantation recipients who may wish to become blood or plasma donors.

Furthermore, FDA already has safeguards in place to ensure that xenotransplantation recipients do not become blood or plasma donors. In the United States all xenotransplantation products and procedures are experimental and must be performed in accordance with FDA-approved research protocols. As a part of these protocols, investigators are required to counsel recipients and their close contacts not to donate blood, plasma, tissue or organs.

Based on the current donor screening procedures and the FDA requirements for xenotransplantation research protocols, we believe additional donor screening questions are uncalled-for. However, application of the precautionary principle may mandate some additional measures to address theoretical zoonotic risks. Consequently, we suggest usage of a donor information circular, posters or placards to make xenotransplantation recipients and their close contacts aware of the need to self defer.

Quarantine and Recall For Xenotransplantation Risks Should be Done on a Case-By-Case Basis

A broad quarantine and recall policy based on xenotransplantation exposure in the absence of some identifiable zoonotic risk is unwarranted. Although the likelihood of a xenotransplantation recipient becoming a blood or plasma donor is extremely remote, even one donor could negatively impact the availability of plasma derived medicines. It is more likely that substantial donor confusion about the nature of xenotransplantation and the theoretical risks it may present, will lead to unnecessary quarantines and recalls of plasma and plasma derived-medicines. Consequently, quarantine and recall should be mandated only in the face of an identified zoonotic risk.

FDA mandated research protocols for xenotransplantation procedures provide a meaningful opportunity to identify potential zoonotic risks in xenotransplantation recipients. Currently, research protocols require that recipients be tracked over time and that their health be closely monitored for evidence of zoonoses and other sequelae. Part of this monitoring includes a national registry of xenotransplantation recipients so that recipients can be easily contacted.

Similarly, the animal cells lines used for xenotransplantation are typically highly characterized. Donor animals are carefully bred and screened for any signs or symptoms of disease long before host cells are harvested. These animals and the harvested cells are maintained in highly controlled environments and routinely evaluated to ensure their suitability for the intended procedure or product.

In light of the careful animal and cell selection procedures, in addition to the recipient tracking and health monitoring, broad quarantine and recall policies are unnecessary. While quarantine and recall may be justifiable in the face of an identified zoonotic risk, the need for continued availability of plasma-derived medicines must prevail in the absence of such risk. Consequently, quarantine and recall of plasma and plasma derived medicines for potential zoonotic risks should be done on a case by case basis and only in the face of identified zoonotic risk.

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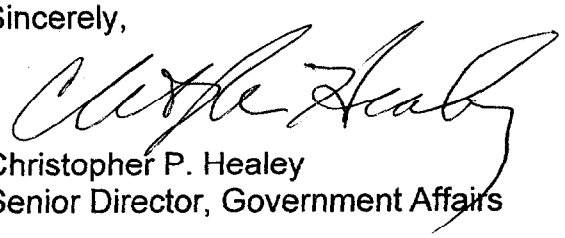
ABRA applauds the Agency's efforts to identify and address potential threats to the blood supply. In cases of theoretical risks, such as zoonoses transmission from xenotransplantation, the Agency must balance the perceived benefits of taking action against the real effects that such action may have on the availability of blood and blood products. In this case, ABRA believes that the negative consequences of additional donor screening and broad quarantine and recall policies outweigh the perceived benefit of attempting to screen-out potential donors who may or may not have been exposed to zoonotic risks.

We appreciate the opportunity to comment on the Draft Guidance and look forward to future revisions of the document. Please feel free to contact me at the number listed above regarding any questions or comments you may have about these comments.

Sincerely,



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